# RIPPLE – Investigator Training

**2014APR28**

NCIC Clinical Trials Group
NCIC Groupe des essais cliniques

# What Is RIPPLE?

## Roster Interface Program & Participants List Environment

A *single electronic system* with 2 major components:

- Member account information
- Participant List administration

RIPPLE can be accessed via the NCIC CTG website

# How Will This Impact Investigators (1)?

Membership Account

- Contains your current contact info, credentialing info (e.g. GCP certificates), trial roles
- Upload of documents (such as NIH)
- All future account changes will be made within the RIPPLE system
- Can be done by yourself or your centre Remote Roster Administrator (RRA) for you

# RIPPLE
# Member Registration

## Personal Information

| | |
|---|---|
| Name | Dr. First* Bruce Middle Last* Banner |
| Account User ID* | The User ID that you will use to login to Ripple and other NCIC CTG systems. The default is your first initial and your last name. thehulk |
| Email* | This address will be used to send you notifications from Ripple. mean@nd.green |
| Verify Email* | mean@nd.green |

## Address Information

| | |
|---|---|
| Centre* | Select your your centre/institution. CANC - NCIC Clinical Trials Group, Queen's University, Kingston ON |
| Address* | 10 Stuart Street |
| Address (Cont.) | |
| City* | Kingston |
| Province* | Ontario |
| Postal Code* | eg. A9A 9A9. K7L 3N6 |
| Phone Number* | eg. 123 456-7890 ext: 123456. 613 533-6430 Ext# |
| Fax Number | eg. 123 456-7890. 613 533-2941 |

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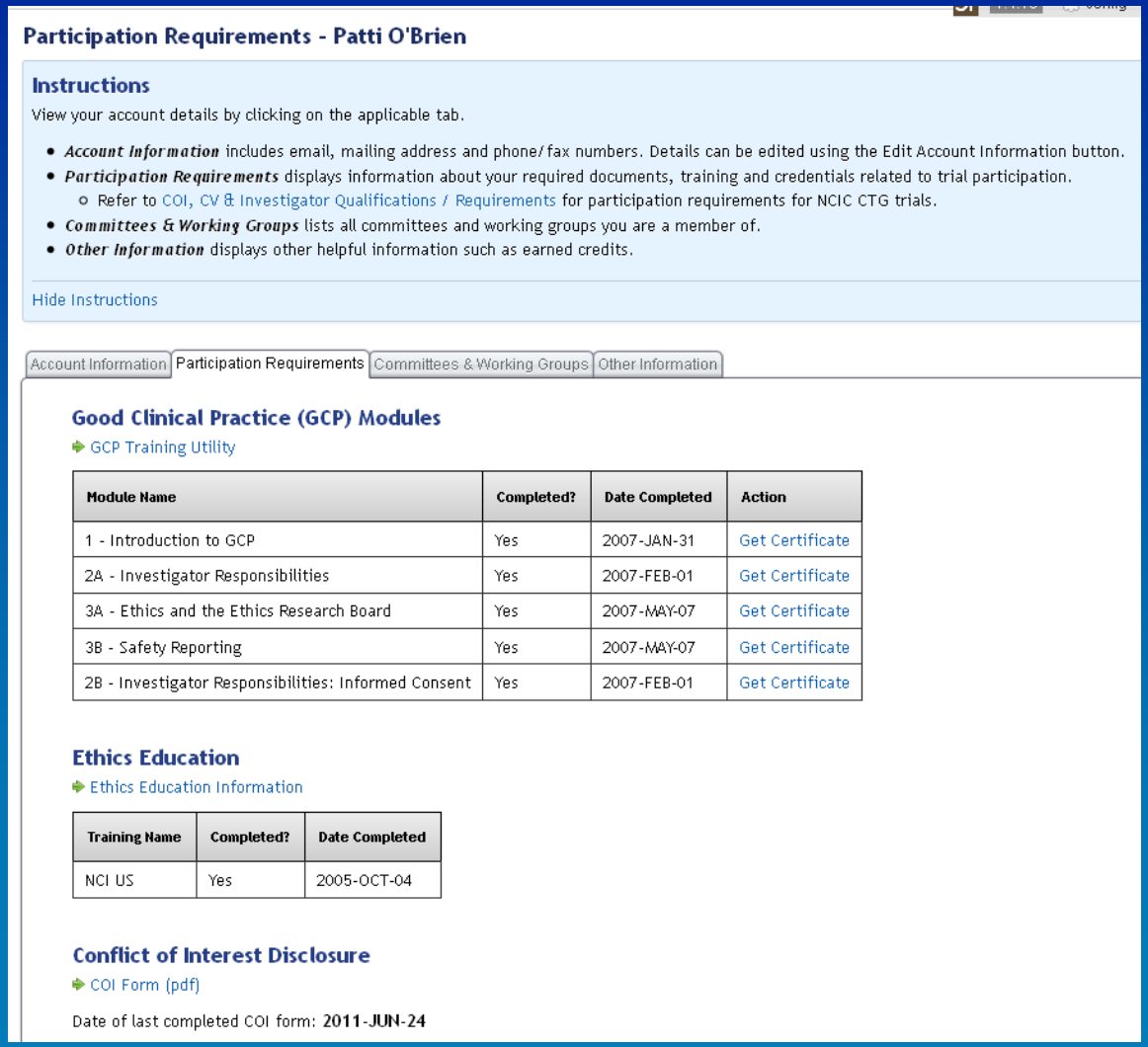
# RIPPLE
# Participant Training Requirements



## Participation Requirements - Patti O'Brien

### Instructions

View your account details by clicking on the applicable tab.

- ***Account Information*** includes email, mailing address and phone/fax numbers. Details can be edited using the Edit Account Information button.
- ***Participation Requirements*** displays information about your required documents, training and credentials related to trial participation.
  - Refer to COI, CV & Investigator Qualifications / Requirements for participation requirements for NCIC CTG trials.
- ***Committees & Working Groups*** lists all committees and working groups you are a member of.
- ***Other Information*** displays other helpful information such as earned credits.

Hide Instructions

Account Information | Participation Requirements | Committees & Working Groups | Other Information

### Good Clinical Practice (GCP) Modules

GCP Training Utility

| Module Name | Completed? | Date Completed | Action |
|---|---|---|---|
| 1 - Introduction to GCP | Yes | 2007-JAN-31 | Get Certificate |
| 2A - Investigator Responsibilities | Yes | 2007-FEB-01 | Get Certificate |
| 3A - Ethics and the Ethics Research Board | Yes | 2007-MAY-07 | Get Certificate |
| 3B - Safety Reporting | Yes | 2007-MAY-07 | Get Certificate |
| 2B - Investigator Responsibilities: Informed Consent | Yes | 2007-FEB-01 | Get Certificate |

### Ethics Education

Ethics Education Information

| Training Name | Completed? | Date Completed |
|---|---|---|
| NCI US | Yes | 2005-OCT-04 |

### Conflict of Interest Disclosure

COI Form (pdf)

Date of last completed COI form: **2011-JUN-24**

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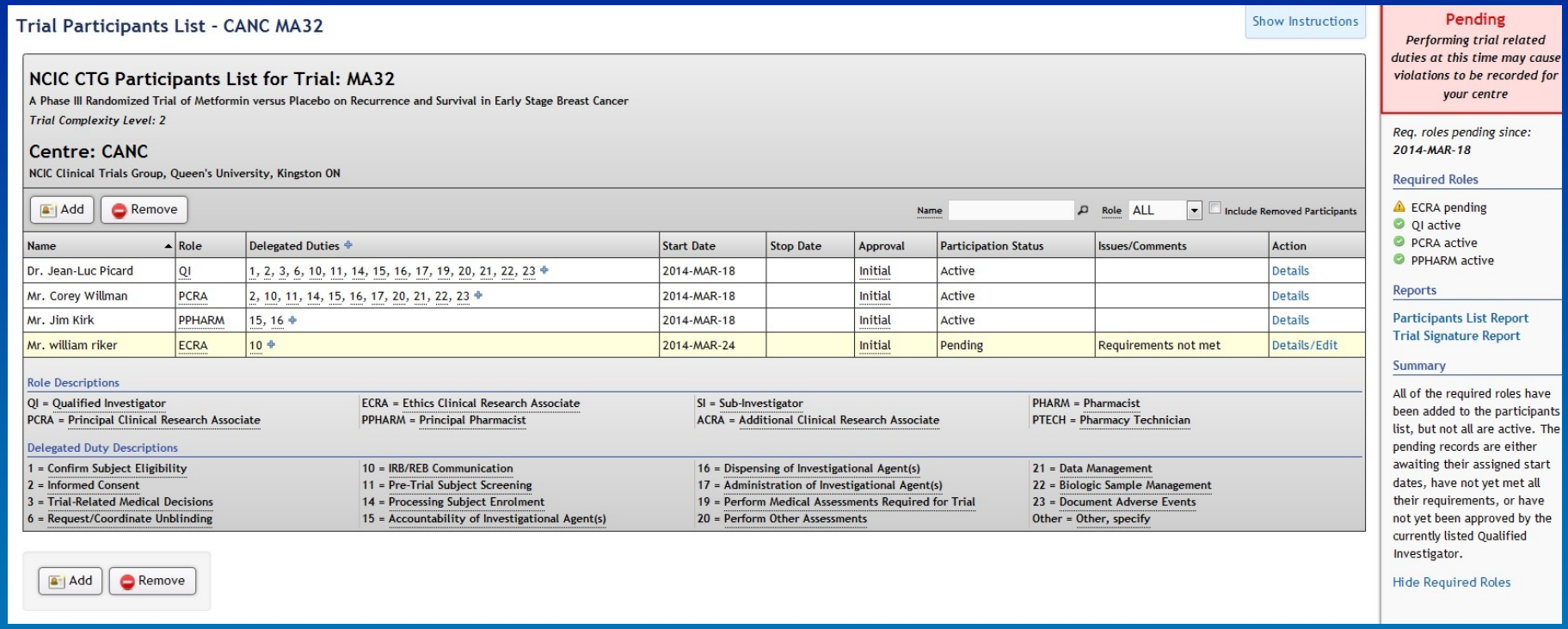
# How Will This Impact Investigators (2)?

Participants Lists

- Participants lists (including QI delegation of duties) for selected trials will be managed in RIPPLE
- Changes in participants, roles, duties and start and stop dates for these trials will be made in the RIPPLE system by appointed centre staff (e.g. RRAs and PLAs)
- All changes to participants lists for trials in RIPPLE must be approved by the QI within the RIPPLE system prior to the changes being effective

# RIPPLE – Participants List



Trial Participants List - CANC MA32

Show Instructions

**NCIC CTG Participants List for Trial: MA32**

A Phase III Randomized Trial of Metformin versus Placebo on Recurrence and Survival in Early Stage Breast Cancer

*Trial Complexity Level: 2*

**Centre: CANC**

NCIC Clinical Trials Group, Queen's University, Kingston ON

Add | Remove

Name | Role ALL | Include Removed Participants

| Name | Role | Delegated Duties | Start Date | Stop Date | Approval | Participation Status | Issues/Comments | Action |
|---|---|---|---|---|---|---|---|---|
| Dr. Jean-Luc Picard | QI | 1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23 | 2014-MAR-18 | | Initial | Active | | Details |
| Mr. Corey Willman | PCRA | 2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23 | 2014-MAR-18 | | Initial | Active | | Details |
| Mr. Jim Kirk | PPHARM | 15, 16 | 2014-MAR-18 | | Initial | Active | | Details |
| Mr. william riker | ECRA | 10 | 2014-MAR-24 | | Initial | Pending | Requirements not met | Details/Edit |

Role Descriptions

QI = Qualified Investigator
PCRA = Principal Clinical Research Associate
ECRA = Ethics Clinical Research Associate
PPHARM = Principal Pharmacist
SI = Sub-Investigator
ACRA = Additional Clinical Research Associate
PHARM = Pharmacist
PTECH = Pharmacy Technician

Delegated Duty Descriptions

1 = Confirm Subject Eligibility
2 = Informed Consent
3 = Trial-Related Medical Decisions
6 = Request/Coordinate Unblinding
10 = IRB/REB Communication
11 = Pre-Trial Subject Screening
14 = Processing Subject Enrolment
15 = Accountability of Investigational Agent(s)
16 = Dispensing of Investigational Agent(s)
17 = Administration of Investigational Agent(s)
19 = Perform Medical Assessments Required for Trial
20 = Perform Other Assessments
21 = Data Management
22 = Biologic Sample Management
23 = Document Adverse Events
Other = Other, specify

Add | Remove

**Pending**

*Performing trial related duties at this time may cause violations to be recorded for your centre*

*Req. roles pending since: 2014-MAR-18*

Required Roles

- ECRA pending
- QI active
- PCRA active
- PPHARM active

Reports

Participants List Report
Trial Signature Report

Summary

All of the required roles have been added to the participants list, but not all are active. The pending records are either awaiting their assigned start dates, have not yet met all their requirements, or have not yet been approved by the currently listed Qualified Investigator.

Hide Required Roles

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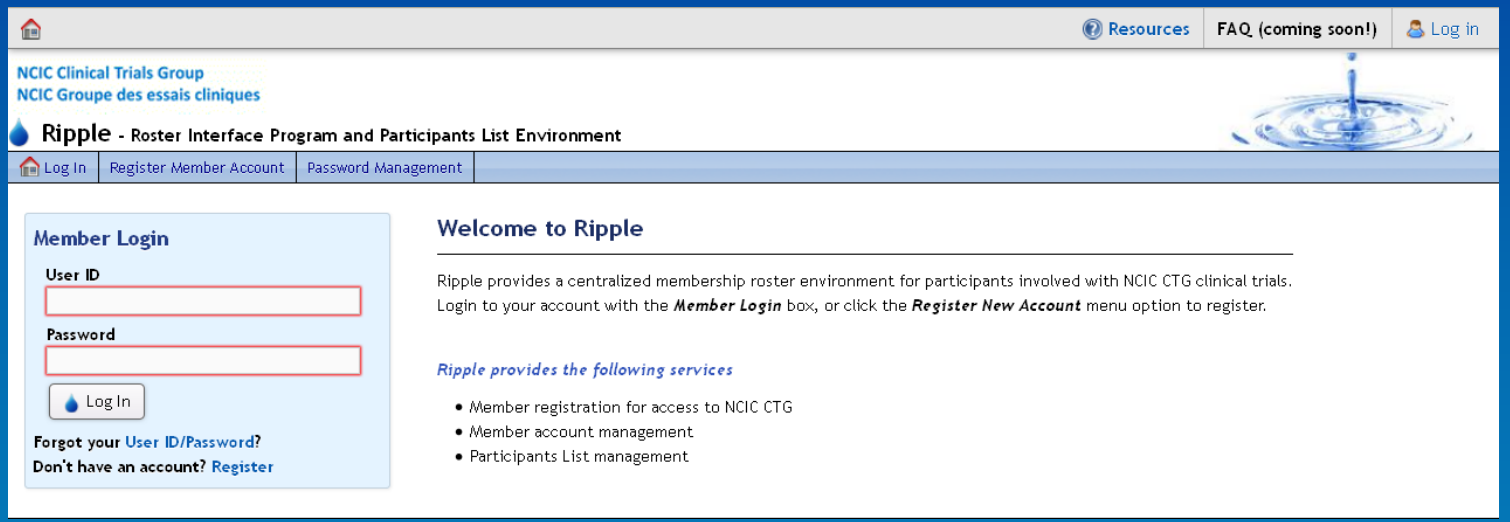
# How do you access RIPPLE?

- RIPPLE is located on the CTG main page


- Use CTG user name/password

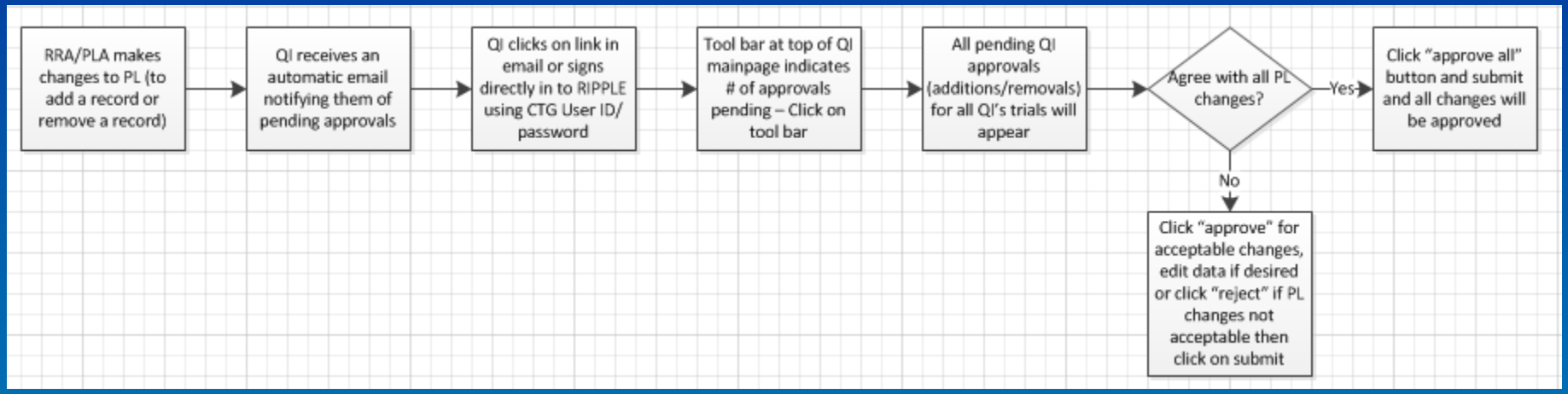



- Forgot your user ID/password? There is a link on the RIPPLE page

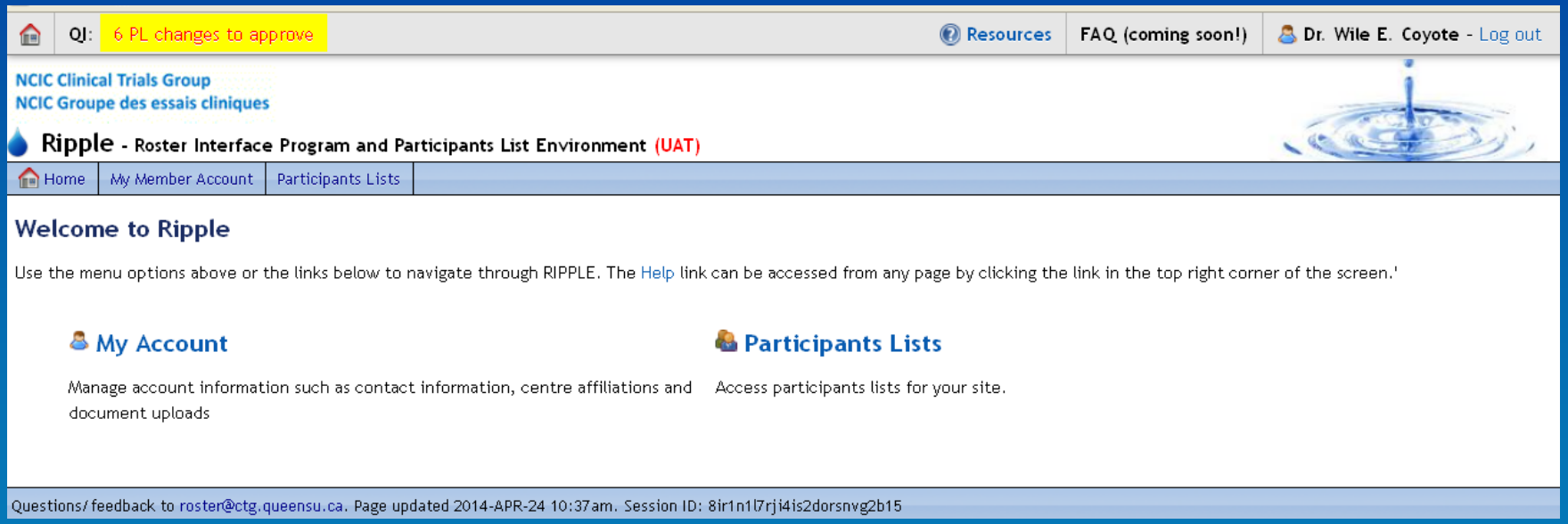
# How Do You Approve PL Changes in RIPPLE?

- Once change to PL made in RIPPLE by centre staff, QI will receive an email notification
- Simply click on link in email
- Enter CTG user ID/password when prompted
- Click on top tool bar link to items requiring QI approval
- All changes requiring QI approval for all your trials will appear on a single screen – changes can be edited (if desired) and each change can be approved separately or approve all at once – you can also reject PL changes

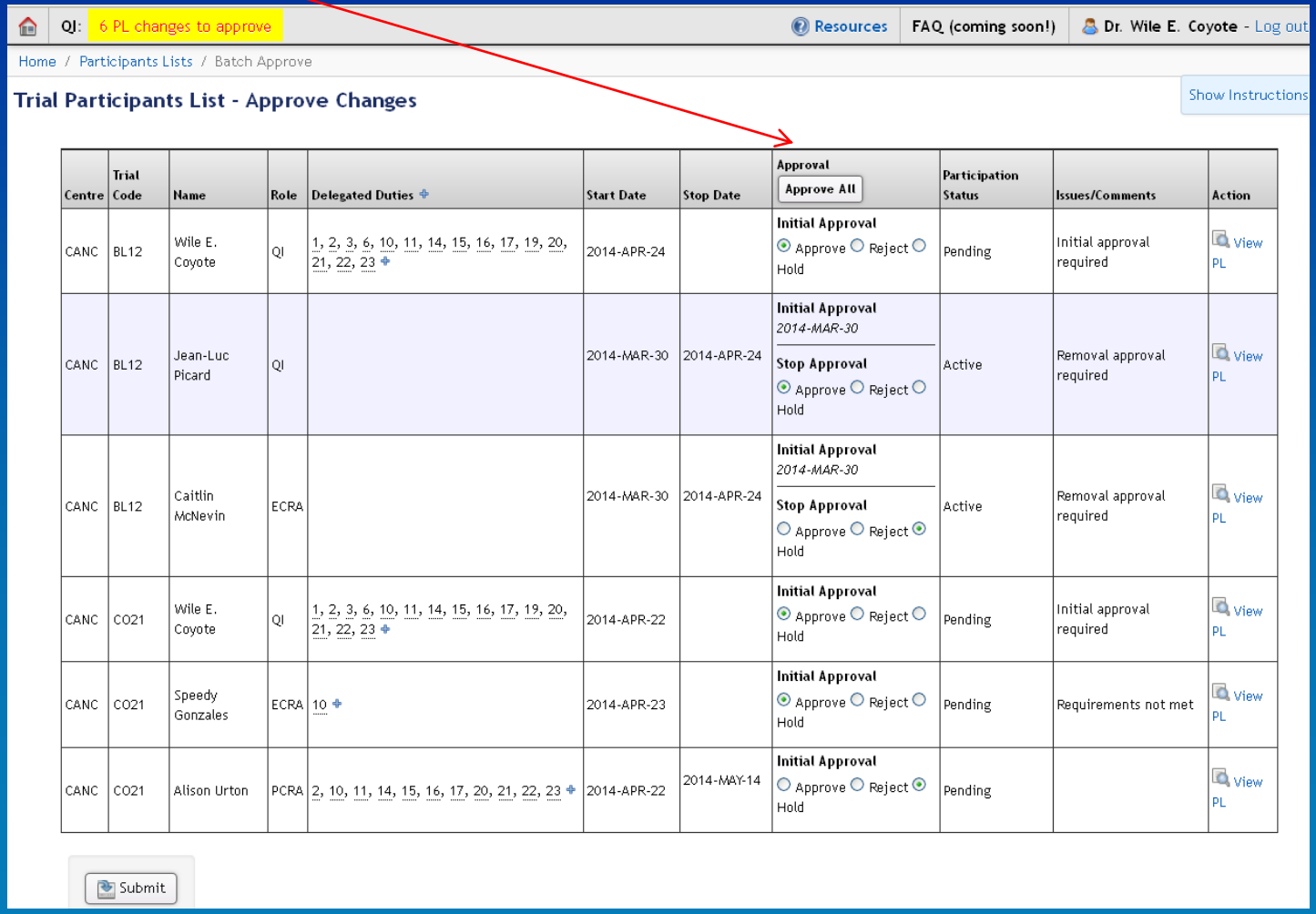
# QI Approval Process



Once you have signed in to your account – the tool bar shows if/how many changes pending QI approval – click on highlighted area



# To approve either click “approve” for each item or click “approve all” which will approve all pending PL changes, can also edit or “reject” PL changes




| Centre | Trial Code | Name | Role | Delegated Duties | Start Date | Stop Date | Approval (Approve All) | Participation Status | Issues/Comments | Action |
|---|---|---|---|---|---|---|---|---|---|---|
| CANC | BL12 | Wile E. Coyote | QI | 1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23 | 2014-APR-24 | | Initial Approval: Approve / Reject / Hold | Pending | Initial approval required | View PL |
| CANC | BL12 | Jean-Luc Picard | QI | | 2014-MAR-30 | 2014-APR-24 | Initial Approval 2014-MAR-30; Stop Approval: Approve / Reject / Hold | Active | Removal approval required | View PL |
| CANC | BL12 | Caitlin McNevin | ECRA | | 2014-MAR-30 | 2014-APR-24 | Initial Approval 2014-MAR-30; Stop Approval: Approve / Reject / Hold | Active | Removal approval required | View PL |
| CANC | CO21 | Wile E. Coyote | QI | 1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23 | 2014-APR-22 | | Initial Approval: Approve / Reject / Hold | Pending | Initial approval required | View PL |
| CANC | CO21 | Speedy Gonzales | ECRA | 10 | 2014-APR-23 | | Initial Approval: Approve / Reject / Hold | Pending | Requirements not met | View PL |
| CANC | CO21 | Alison Urton | PCRA | 2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23 | 2014-APR-22 | 2014-MAY-14 | Initial Approval: Approve / Reject / Hold | Pending | | View PL |

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# Important Points

- No additions to the PL will be effective until:
  - Requested start date as entered by centre has been reached
  - All credentialing required for that role has been met
  - Addition has been approved by QI in RIPPLE
- Only once all 3 criteria are met does participant's status on trial change to "active" and effective start date is added (the latest of these 3 dates)

# Important Points

- PL removals must also be approved by QI!
- No removals to the PL will be effective until:
  - Requested stop date as entered by site has been reached
  - Stop date has been approved by QI in RIPPLE
- Only once both criteria are met does participant's status on trial change to "removed" and effective stop date is added (the latest of these dates)

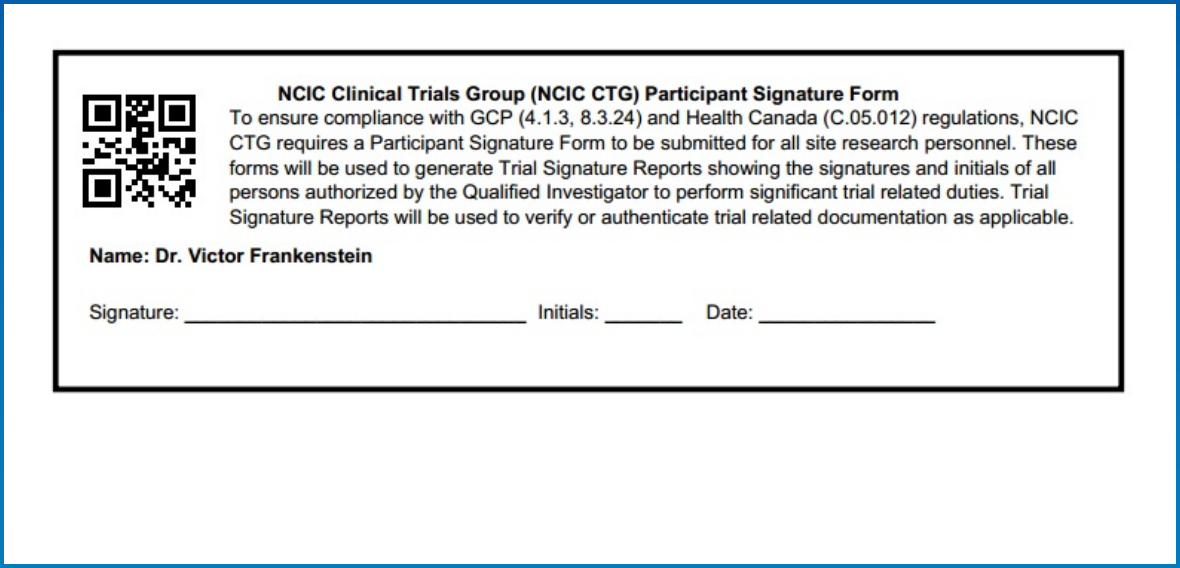
# RRAs and PLAs

Two new roles for RIPPLE:

- Remote Roster Administrator (RRA)
  - Add/approve/edit/remove member accounts
  - Create/edit trial PLs
  - Receiving notifications of member account/PL issues
- Participants List Administrator (PLA)
  - Create/edit trial PL

# Participant Signatures

- Signature sheet is an essential document for trials according to GCP
- One-time only Participant Signature Form (PSF) to be submitted for all site research personnel active on trials (RRA can upload)



**NCIC Clinical Trials Group (NCIC CTG) Participant Signature Form**

To ensure compliance with GCP (4.1.3, 8.3.24) and Health Canada (C.05.012) regulations, NCIC CTG requires a Participant Signature Form to be submitted for all site research personnel. These forms will be used to generate Trial Signature Reports showing the signatures and initials of all persons authorized by the Qualified Investigator to perform significant trial related duties. Trial Signature Reports will be used to verify or authenticate trial related documentation as applicable.

**Name: Dr. Victor Frankenstein**

Signature: _____ Initials: _____ Date: _____

# How Is This System Easier For You?

- All QI approvals can be done from anywhere with only a few quick clicks
- All changes for all trials can be approved at once with a single click in the QI approval screen
- No more paper forms to sign each time a change to any PL is made
- Batch email notifications and reminders
- Can view trial or your member record information easily in the system anytime
- Majority of changes/updates in system done by other centre staff

# When Is This Happening?

- 2014APR28
  - Membership account information for all Canadian CTG members will be accessible in RIPPLE (regardless of trial assignment)
  - MA.32 Participants Lists will be available in RIPPLE
- Other trials to follow shortly afterwards and you will be notified by memos prior to each trial being moved into RIPPLE

# Where To Go For Help

- Many of your CRAs will have already completed webinar training
- Useful resources will be available in the RIPPLE system including
  - Training slide decks
  - Copies of Memos and external bulletins
  - Frequently asked questions
  - Forms
  - ripple@ctg.queensu.ca